

K070146

## Premarket Notification [510(k)] Summary

007 1 2 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K070146

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Contact Persons: Olivier Ducamp (oducamp@fr.abx.fr)  
Caroline Ferrer (cferrer@fr.abx.fr)

Date Prepared: 24<sup>th</sup> September 2007

### Device Names:

The following reagents, controls & calibrators are for use in conjunction with the ABX PENTRA 400, cleared to market under K052007.

### REAGENT :

Trade/Proprietary Name:	<b>ABX PENTRA Urea CP</b>
Common or Usual Name:	Urea / Urea Nitrogen
Device Class	Class II
Classification Name:	§862.1770 : Urea nitrogen Test System
Product Code:	CDQ ; urease and glutamic dehydrogenase, urea nitrogen

### CONTROL :

Trade/Proprietary Name:	<b>ABX PENTRA Urine Control L/H</b>
Common or Usual Name:	Urine control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed)

**Substantial Equivalence:**

The data and information supplied in this submission demonstrates substantial equivalence to their respective predicate devices:

Submission device	Substantially equivalent Predicate device
ABX PENTRA Urea CP	K971477
ABX PENTRA Urine Control L/H	K070249

**Description:**

All the reagents, controls and calibrators included in this submission are for use on the **ABX PENTRA 400** (K052007), which is a discrete photometric benchtop clinical chemistry analyzer.

The **ABX PENTRA Urea CP** is an in vitro diagnostic assay for the quantitative determination of urea / urea nitrogen (an end-product of nitrogen metabolism) in human serum, plasma and urine based on an enzymatic UV test using urease and glutamate dehydrogenase. It is composed of a bi-reagent cassette, with 60 ml and 15 ml compartments. Reagents are chemical solutions with additives.

The **ABX PENTRA Urine Control L/H** is a two-level (Low and High) quality control consisting of liquid solutions prepared from human urine with chemical additives and materials of biological origin added as required to obtain given component levels. The assigned values of the control components are given in the enclosed annex, ensuring control of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer. Each control level is provided in one vial of 10 ml.

**Intended Use:**

The reagents in this submission are intended for use on the **ABX PENTRA 400** for the quantitative in-vitro determination of the respective analyte (Urea / Blood Urea Nitrogen) using human serum, plasma and urine.

The controls and calibrators are intended for use in association with the above reagent.

**Discussion of Performance Data:**

ABX Pentra Urea CP (K060205) has already been cleared by the FDA for use on serum and plasma samples. No modification has been made to this device. The performances on serum and plasma samples have not been modified.

Therefore, for this device, only added performances, on urine samples, are discussed in the following pages.

## REAGENT

<b>ABX PENTRA Urea CP :</b>	
Sample type	Urine
Detection limit	Urea: 12.6 mmol/l BUN: 35 mg/dl
Accuracy and Precision	CV Total < 7.50%
Measuring range	Urea : 12.6 mmol/l – 750.0 mmol/l BUN: 35 mg/dl – 2106 mg/dl
Upper linearity limit	Urea: 750 mmol/l and with automatic post-dilution: 3750 mmol/l BUN: 35 mg/dl and with automatic post-dilution : 2106 mg/dl
Correlation (n=147):	Urea: $Y = 1.13 x - 0.71$ with a correlation coefficient $r^2 = 0.9947$ . BUN: $Y = 1.13 x - 2.08$ with a correlation coefficient $r^2 = 0.9947$ .
Calibration stability	8 days
Reagent stability	closed stability: 24 months at 2-8°C on-board stability (refrigerated area): 70 days

## CONTROL

<b>ABX PENTRA Urine Control L/H:</b>		
Analytes	Already cleared	Included in this submission
Amylase	√ (K070249)	
Calcium	√ (K070249)	
Creatinine	√ (K070249)	
Phosphorus	√ (K070249)	
Glucose*		
Urea / Blood Urea Nitrogen		
Uric acid*		
Urinary proteins	√ (510k exempt)	
Chloride*		
Potassium*		
Sodium*		
Format	Liquid solution prepared from human urine with chemical additives and materials of biological origin	
Stability	Closed stability: 2 years at 2-8°C Open stability: 30 days at 2-8°C	

\* Not cleared as of date of submission

**Conclusions for Performance Testing:**

The performance testing data conclude that the safety and effectiveness of the devices are not compromised, and that they met all acceptance criteria, demonstrating that the devices are substantially equivalent to their respective predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Horiba ABX  
c/o Mr. Olivier Ducamp  
Regulatory Affairs Manager  
Parc Euromédecine  
Rue du Caducée – BP 7290  
34184 Montpellier cedex 4 France

OCT 12 2007

Re: k070146  
Trade/Device Name: ABX PENTRA Urea CP, Urine Control L/H  
Regulation Number: 21 CFR§862.1770  
Regulation Name: Urea Nitrogen Test System  
Regulatory Class: Class II  
Product Code: CDQ, JJY  
Dated: September 24, 2007  
Received: September 27, 2007

Dear Mr. Ducamp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "Jean M. Cooper, M.S., D.V.M.".

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K070146

Device Name: ABX PENTRA Urea CP

Indications For Use:

ABX PENTRA Urea CP reagent with associated calibrators and controls are intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer for quantitative in vitro diagnostic determination of urea / urea nitrogen (an end-product of nitrogen metabolism) in human serum, plasma and urine based on an enzymatic UV test using urease and glutamate dehydrogenase. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

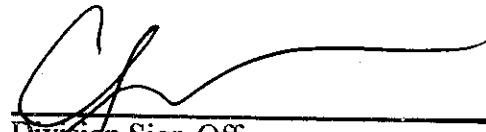
AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

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## Indications for Use

510(k) Number (if known): K070146

Device Name: ABX PENTRA Urine Control L/H

Indications For Use:

The ABX PENTRA Urine Control L/H is for use in quality control by monitoring accuracy and precision.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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